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10/665,389	09/18/2003	Mark W. McGarry	067456-5052US01	4217

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EXAMINER
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BEISNER, WILLIAM H

ART UNIT	PAPER NUMBER
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1744

MAIL DATE	DELIVERY MODE
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09/20/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No. 10/665,389	Applicant(s) MCGARRY ET AL.	
	Examiner William H. Beisner	Art Unit 1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 04 June 2007 and 29 June 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1, 5-7 and 9-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 5-7 and 9-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Drawings***

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the “third port” and “pump” must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

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pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1, 5, 6, 11-16 and 21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Amended claim 1 recites that the reaction chamber includes “a first port”, “a second port” and “a third port”. The originally filed disclosure appears to only provide support for “a first port” (38) and “a second port” (39). The Examiner cannot find support for “a third port”. Applicants have not pointed to any disclosure of “a third point” when making the amendment to claim 1. As a result, the specification fails to reasonably convey to one of ordinary skill in the art that the inventor, at the time of filing the application, had possession of the claimed invention now recited in claim 1.

### ***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 7 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Fodor et al.(US 5,324,633).

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With respect to claim 7, the reference of Fodor et al. discloses an apparatus for performing biological reactions on a substrate layer that includes including a substrate (212) and a plurality of reactive sites on the substrate (See column 12, lines 13-36). The apparatus includes a base plate (202 or 329) having a cavity or well structure (204 or 310) and a sealing member (See column 8, lines 31-39, or element (335)) affixed between the substrate and the base plate (See Figure 3c and column 12, lines 13-36), the sealing member defining a well structures (204 310), each reaction chamber corresponding to one of the reactive sites. The device also includes a pump (216) that is capable of mixing and pressurizing a fluid sample in the reaction chamber (204) and a port (208) connected to interface the pump (216) with at least one reaction chamber (204).

With respect to claim 9, the biological reactive sites can include oligonucleotide probes (See column 4, lines 42-44 and claim 21).

### ***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

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2. Ascertaining the differences between the prior art and the claims at issue.
  3. Resolving the level of ordinary skill in the pertinent art.
  4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
9. Claims 1, 5 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fodor et al.(US 5,324,633).

The reference of Fodor et al. has been discussed above.

Claim 1 differs by reciting that the device includes a second and third port.

While the reference of Fodor et al. discloses the use of a second port (210), the reference is silent to the use of an additionally “third port” in fluid communication with the reaction chamber.

However, in the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art to provide the device within an additional fluid port for the known and expected result of allowing additional fluid to be contacted with the reaction chamber, for example, additional or separate reagents. Note the mere duplication of

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parts has no patentable significance unless a new and unexpected result is produced. In re Harza, 274 F.2d 669, 124 USPQ 378 (CCPA 1960).

With respect to claim 5, the biological reactive sites can include oligonucleotide probes (See column 4, lines 42-44 and claim 21).

With respect to claim 11, the reference of Fodor et al. discloses the use of gaskets and clamps or vacuum (See column 8, lines 31-39, and column 12, lines 17-26).

10. Claims 6 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fodor et al.(US 5,324,633) in view of Trulson et al.(US 5,578,832).

The reference of Fodor et al. has been discussed above.

Claims 6 and 10 differ by reciting that the apparatus includes a heating element positioned to heat at least one reaction chamber.

The reference of Trulson et al. discloses that when performing a reaction in a flow cell similar to that of the primary reference, it is known in the art to provide the flow cell with a temperature controller which can include a heating element (See column 9, lines 50-65).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the flow cell of the primary reference with a temperature controller for the known and expected result of controlling the reaction conditions within the flow cell.

11. Claims 12-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fodor et al.(US 5,324,633) in view of Turner (US 5,571,721).

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The reference of Fodor et al. has been discussed above.

While the reference of Fodor et al. discloses the use of a gasket sealing means, the reference is silent as to the material of the sealing gasket.

The reference of Turner discloses that it is conventional in the art to provide a number of sealing structures for forming a chamber on the surface of a slide substrate (See column 1, lines 30-59, and column 2, lines 38-61).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to employ any of the gasket or sealing material disclosed by the reference of Turner to form the reaction chamber of the primary for the known and expected result of providing an art recognized material for forming a chamber on a slide substrate.

### ***Double Patenting***

12. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).



13. Claims 1, 5-7 and 9-22 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-17, 19-30 and 33-66 of U.S. Patent No. 6,642,046 in view of Fodor et al. (US 5,324,633).

Claims 1-17, 19-30 and 33-66 of U.S. Patent No. 6,642,046 encompass a device that is substantially the same as that instantly recited in claims 1, 5-7 and 9-22. The device of claims 1-17, 19-30 and 33-66 of U.S. Patent No. 6,642,046 includes all of the positively recited structures of instant claim 1, 5-7 and 9-22 except for the instantly claimed pump structure.

The reference of Fodor et al. discloses that it is conventional in the art to employ a pump device for controlling the flow of fluids into and out of a reaction chamber device that is similar to that of the patented claims.

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the device of the patented claims with a pump structure for the known and expected result of providing a means recognized in the art for controlling the flow of fluids into and out of the reaction chamber of the substrate device.

With respect to the third port of Claim 1, while the patented claims and the reference of Fodor et al. discloses the use of a first and a second port, the claims and reference are silent to the use of an additionally "third port" in fluid communication with the reaction chamber.

However, in the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art to provide the device within an additional fluid port for the known and expected result of allowing additional fluid to be contacted with the reaction chamber, for example, additional or separate reagents. Note the mere duplication of

parts has no patentable significance unless a new and unexpected result is produced. In re Harza, 274 F.2d 669, 124 USPQ 378 (CCPA 1960).

***Response to Arguments***

14. With respect to the rejection of Claims 1-5 and 7-9 under 35 U.S.C. 102(b) as being anticipated by Fodor et al.(US 5,324,633), Applicants argue that the rejection is improper because the reference of Fodor et al. does not disclose “a third port” or “a pump” as are now recited in claims 1 and/or 7 (See page 5 of the response filed 6/4/2007).

In response, for the reasons set forth in the rejection of claim 7 above under 35 USC 102(b), the Examiner is of the position that claim 7 is anticipated by the reference of Fodor et al. because the reference disclose the use of a pump in the system.

With respect to claim 1, the Examiner is of the position that the recitation of “a third port” is not a patentable distinction and would have been obvious to one of ordinary skill in the art.

15. The rejection of Claims 1-10 under 35 U.S.C. 102(a) or (e) as being anticipated by Schembri et al.(US 6,258,593) has been withdrawn in view of Applicants' amendments to the claims and related comments (See pages 5-6 of the response filed 6/4/2007).

16. With respect to the rejection of Claims 6 and 10 under 35 U.S.C. 103(a) as being unpatentable over Fodor et al.(US 5,324,633) in view of Trulson et al.(US 5,578,832), Applicants argue that neither of the references of Fodor et al. and Trulson et al. disclose “a third

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port” or “pump” required of amended claims 1 and/or 7 (See pages 6-7 of the response filed 6/4/2007).

In response, for the reasons set forth in the rejection of claim 7 above under 35 USC 102(b), the Examiner is of the position that claim 7 is anticipated by the reference of Fodor et al. because the reference disclose the use of a pump in the system.

With respect to claim 1, the Examiner is of the position that the recitation of “a third port” is not a patentable distinction and would have been obvious to one of ordinary skill in the art.

17. With respect to the rejection of Claims 1-10 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-17, 19-30 and 33-66 of U.S. Patent No. 6,642,046, Applicants argue that the patented claims fail to disclose “a third port” or “pump” required of amended claims 1 and/or 7 (See pages 7-8 of the response filed 6/4/2007).

In response, Applicants’ comments are considered moot since the rejection has been modified to include the reference of Fodor et al. (US 5,324,633) to address the newly recited “a third port” and “a pump”.

### ***Conclusion***

18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 571-272-1269. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:15am to 3:45pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys J. Corcoran can be reached on 571-272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/William H. Beisner/  
Primary Examiner  
Art Unit 1744

WHB